REMARKS

I. Status of the Application

This paper responds to a Final Office Action mailed December 01, 2006. The original application was filed with claims 1-17. In a response to a telephonic restriction requirement, Applicant elected to pursue Group I invention (claims 1-9) and gabapentin species. A non-final Office action mailed on September 13, 2001 rejected claims 1-9 and withdrew from consideration claims 10-17 as being drawn to a non-elected invention. Applicant filed a response to the non-final Office action on February 12, 2002, amending claims 1-9 and adding new claims 18-22. A subsequent final Office action mailed on May 30, 2002, rejected claims 1-9 and 18-22. Applicant filed an after-final amendment on July 30, 2002, which was not entered. Applicant subsequently filed a Request for Continued Examination (RCE), which amended claim 1 and added new claims 23 and 24. A non-final Office action mailed April 10, 2003 rejected claims 1-9 and 18-24. Applicant filed a response to the non-final Office action on September 10, 2003, amending claims 1, 9, 18, 20, and 24. A subsequent final Office action mailed January 7, 2004, rejected claims 1-9 and 18-24. Applicant filed a response to the final Office action on April 7, 2004, and cancelled claims 1-9 and 18-24 and requested entry of new claims 25-31 and subsequently filed an RCE on June 7, 2004. A subsequent non-final action mailed January 27, 2005 rejected claims 25-31 and withdrew claim 32 from consideration since the claim was drawn to a non-elected invention. Applicant filed a response to the non-final Office action on May 27, 2005, amending claims 25, 29, and 30, withdrawing claim 32, and adding new claim 33. A subsequent final Office action mailed August 25, 2005 rejected claims 25-31 and 33. Applicant responded to the final Office action on November 21, 2005 and amended claim 25, cancelled claim 29-30, and added new claims 34-38. An RCE was also submitted with the response. A non-final Office action mailed February 3, 2006 rejected claims 25-28, 31, and 33-38. Applicant responded to the non-final Office action on May 3, 2006 and amended claims 25 and 34, and added new claim 39. A subsequent non-final Office action mailed June 28, 2006 rejected claims 25-28, 31, and 33-39. Applicant responded to the non-final Office action September 28, 2006 and

cancelled claims 25-28, 31, 33, and 39, and amended claims 34-37. A subsequent final Office action mailed December 1, 2006 rejected claims 34-38.

In this paper, Applicant amends claims 34 and 38 and adds new claim 40. Applicant respectfully submits that entry of the amendment is proper because the amended claims are in condition for allowance. Claims 34-38 and 40 are pending in the application.

II. Rejection of Claims Under 35 U.S.C. § 103(a)

The Final Office Action rejected all of the pending claims under §103(a) as being unpatentable over Robson et al. (US 4,126,684) in view of Costa et al. (US 5,248,678) and further in view of Bays et al. (WO 96/11680). Applicant asserts that the claims are patentable over Robson in view of Costa and Bays. Claims 34-38 are drawn to a stable pharmaceutical composition comprising a neutral alpha amino acid and gabapentin or pregabalin. Applicant respectfully submits that the rejection, as applied to claims 34-38, is improper because (A) it does not establish a prima facie case of obviousness and (B) the Ofice has disregarded data in the specification that shows that the claimed compositions achieve surprising and unexpected results.

(A) Prima Facie Obviousness

To establish a prima facie case of obviousness, there must be (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; there must be (2) a reasonable expectation of success; and (3) the reference (or references when combined) must teach or suggest all the claim limitations. (MPEP 2143.01) Applicant respectfully submits that there is no suggestion or motivation to combine Robson et al., Costa et al., and Bays et al., and that for reasons of record and further reasons detailed below, the Office has not met its burden of establishing a prima facie case of obviousness; therefore, the rejection is improper.

Applicant respectfully submits that there is no motivation to modify the references or to combine the references. The claimed invention relates to a stable pharmaceutical composition comprising a neutral alpha amino acid, gabapentin or pregabalin, and optionally, one or more auxiliary agents. According to the Office action, Robson et. al., discloses a composition comprising a 4-amino-3-substituted butanoic acid derivative such as baclofen, alpha amino acid glycine, auxiliary agent (i.e., sorbitol, mannitol, lactose, etc.,) and aqueous gelatin solution, wherein said composition is prepared in various dosage forms including tablet, capsule, and solution.

Applicant submits that there is no motivation to modify Robson because to do so would render Robson unsuitable for its intended purpose. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed Cir. 1984); MPEP 2143.01. Robson claims a composition comprising an addicting amount of a barbiturate, a narcotic agent and a 4-amino-3-p-halophenylbutyric acid derivative, and a pharmaceutical excipient. A key element of the Robson claim is the addicting amount of a barbiturate and a narcotic agent. Applicant submits that the pharmaceutical compositions only comprise gabapentin or pregabalin as active agents and do not permit the inclusion of a barbiturate and narcotic agent. Thus, there would be no motivation or suggestion from Robson to make the modification as claimed by Applicant.

The Examiner supplied references Costa et al., and Bays et al., to demonstrate that the art recognized the functional equivalent of gabapentin and baclofen as a GABA agonist. Costa et al discloses the administering of effective amounts of an adenosine receptor agonist in combination with a GABA agonist to increase alertness or arousal in a comatose or near-comatose patient. Bays et al., describes the use of GABA agonists for the treatment of emesis. Neither Costa nor Bays provide any motivation or suggestion to formulate gabapentin or pregabalin with an alpha amino acid. Thus, neither of them alone or in combination provide any teaching, suggestion, or motivation, relative to Robson, et al., to formulate a stable solid pharmaceutical composition for gabapentin or pregabalin. Therefore, Applicant requests that the Examiner withdraw the obviousness rejection and allow the claims to grant.

(B) Surprising and Unexpected Results

Applicant respectfully submits that the action has disregarded the surprising and unexpected results of the addition of an alpha amino acid on the stability of gabapentin and pregabalin. As disclosed in the specification, one particular problem with which Applicant was concerned is degredation of gabapentin into toxic corresponding lactam in a finished product. Applicant has discovered that the addition of a neutral alpha amino acid can prevent formation of lactam (lactamization). The data provided in the specification, pages 43- 53, show that the addition of an alpha amino acid reduces the amount of lactamization. In particular, Table 3 (pg. 44) shows that the additional of glycine or L-valine decreased the amount of gabapentin lactamization by about 60%. Further, Table 10 (pg. 52) shows that the addition of glycine and L-valine decrease pregabalin lactamization by about 50%. As such, the results are surprising and unexpected. Furthermore, none of the references cited teach or suggest the stabilizing affect of an alpha amino acid on gabapentin or pregabalin.

III. Double Patenting

The Examiner has maintained the rejection to Claims 34-38 under the judicially created doctrine of double patenting over claims 36-37 of co-pending US Application No. 09/674,819. Applicants previously submitted that the rejection is improper because US Application No. 09/674,819 has not yet issued as a patent and no actual double patenting rejection may be properly made over claims of a co-pending application. (MPEP 804). Applicant will file an appropriate Terminal Disclaimer to subsequent patent applications once a patent grants. Applicants respectfully reiterate this argument and submit that the rejection should be withdrawn

IV. Time for Reply

This paper responds to a final Office action mailed December 1, 2006. The Office action set a shortened statutory period for reply of three months from the mailing

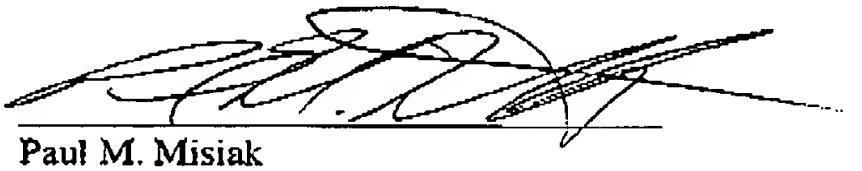
date, making the response due on or before Thursday, March 1, 2007. Applicant is filing this paper on April 2, 2007, which is beyond the three-month period for reply. Applicant respectfully requests a 1-month extension of time pursuant to 37 CFR §1.136. Further, in compliance with USPTO rules (MPEP 510, Applicant is filing this paper on the next business day as April 1 was Sunday, a non-business day. The Commissioner is hereby authorized to charge deposit account number 16-1445 for any appropriate charges associated with the filing of the present amendment.

V. Conclusion

In view of the amendments and foregoing remarks, Applicant respectfully requests reconsideration of the matter, the withdrawal of all rejections, and timely issuance of a Notice of Allowance.

Respectfully submitted,

Date: April 2, 2007



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